

WHAT IS CLAIMED IS:

1. A method for loading a preservative into a biological sample comprising:

providing a preservative solution having a preservative, water and protein; and

loading a biological sample with the preservative solution to produce a preservative-loaded biological sample wherein said preservative solution generally has higher glass transition temperatures than glass transition temperatures for a preservative solution having the preservative, water and no protein.

2. The method of Claim 1 wherein said preservative solution in said preservative-loaded biological sample comprises a gradient of the glass transition temperature (degrees C) to a water content (grams of water per gram of dry weight of preservative and protein) ranging from about 50 to about 900 at a water content of less than about 0.40 grams of water per gram of dry weight of preservative and protein.

3. The method of Claim 1 wherein said glass transition temperature of said preservative solution in said preservative-loaded biological sample increases at a water content of less than about 0.40 grams of water per gram dry weight of preservative and protein.

4. The method of Claim 1 wherein said preservative solution in said preservative-loaded biological sample comprises a greater rate of glass transition temperature per water content (weight of water per dry weight of preservative and protein) increase at

a water content of less than about 0.25 grams of water per gram dry weight of preservative and protein than at a water content greater than about 0.25 grams of water per gram dry weight of preservative and protein.

5. The method of Claim 1 wherein said preservative solution in said preservative-loaded biological sample comprises a greater rate of glass transition temperature per water content (weight of water per dry weight of preservative and protein) increase at a water content of less than about 0.15 grams of water per gram dry weight of preservative and protein than at a water content of greater than about 0.15 grams of water per gram dry weight of preservative and protein.

6. The method of Claim 1 wherein said preservative solution in said produced preservative-loaded biological sample generally has said higher glass transition temperatures at a water content (weight of water per dry weight of preservative and protein) of less than about 0.25 grams of water per gram dry weight of preservative and protein.

7. The method of Claim 1 wherein said preservative comprises an oligosaccharide.

8. The method of Claim 7 wherein said oligosaccharide comprises trehalose.

9. The method of Claim 1 wherein said preservative-loaded biological sample comprise a water content ranging from about 0.02 grams of water per gram of dry weight of preservative and protein to about 0.40 grams of water per gram of dry weight of preservative and protein.

10. The method of Claim 1 wherein said preservative-loaded biological sample comprise a water content ranging from about 0.15 grams of water per gram of dry weight of preservative and protein to about 0.40 grams of water per gram of dry weight of preservative and protein.

11. The method of Claim 1 wherein said protein comprises albumin.

12. The method of Claim 1 wherein said albumin comprises bovine albumin.

13. The method of Claim 1 wherein a gradient of the glass transition temperature (degrees C) to the water content (grams of water per gram of dry weight of preservative and protein) ranges from about 50 to about 900 at a water content of less than about 0.30 grams of water per gram of dry weight of preservative and protein.

14. The method of Claim 1 wherein a gradient of the glass transition temperature (degrees C) to the water content (grams of water per gram of dry weight of preservative and protein) ranges from about 50 to about 900 at a water content ranging from about 0.02 to less than about 0.40 grams of water per gram of dry weight of preservative and protein.

15. The method of Claim 1 wherein a gradient of the glass transition temperature (degrees C) to the water content (grams of water per gram of dry weight of preservative and protein) ranges from about 100 to about 800 at a water content ranging

from about 0.15 to about 0.30 grams of water per gram of dry weight of preservative and protein.

16. The method of Claim 1 wherein a gradient of the glass transition temperature (degrees C) to the water content (grams of water per gram of dry weight of preservative and protein) ranges from about 50 to about 150 at a water content ranging from about 0.20 to about 0.30 grams of water per gram of dry weight of preservative and protein.

17. The method of Claim 1 wherein a gradient of the glass transition temperature (degrees C) to the water content (grams of water per gram of dry weight of preservative and protein) ranges from about 75 to about 125 at a water content ranging from about 0.20 to about 0.30 grams of water per gram of dry weight of preservative and protein.

18. The method of Claim 1 wherein a gradient of the glass transition temperature (degrees C) to the water content (grams of water per gram of dry weight of preservative and protein) ranges from about 700 to about 900 at a water content ranging from about 0.15 to about 0.20 grams of water per gram of dry weight of preservative and protein.

19. The method of Claim 1 wherein a gradient of the glass transition temperature (degrees C) to the water content (grams of water per gram of dry weight of preservative and protein) ranges from about 750 to about 850 at a water content ranging from about 0.15 to about 0.20 grams of water per gram of dry weight of preservative and protein.

20. The method of Claim 1 wherein said preservative solution comprises said preservative and said protein in a weight ratio ranging from about 0.25 grams to about 1.75 grams of preservative per each gram of protein.

21. The method of Claim 1 wherein said preservative solution comprises said preservative and said protein in an approximate 1:1 weight ratio.

22. The method of Claim 1 wherein said preservative-loaded biological sample has said higher glass transition temperatures.

23. The method of Claim 9 wherein said preservative-loaded biological sample has said higher glass transition temperatures.

24. A biological sample produced in accordance with the method of Claim 1.

25. A biological composition comprising
a biological sample having a preservative solution including a preservative, water, and protein, and generally having higher glass transition temperatures than glass transition temperatures for the biological sample loaded with the preservative, water, but no protein.

26. The biological composition of Claim 25 wherein said biological sample comprises a gradient of the glass transition temperature (degrees C) to a water content (grams of water per gram of dry weight biological sample) ranging from about 50 to about 900 at a water content of less than about 0.40 grams of water per gram of dry weight biological sample.

27. The biological composition of Claim 25 wherein a gradient of the glass transition temperature (degrees C) to the water content (grams of water per gram of dry weight of biological sample) ranges from about 50 to about 150 at a water content ranging from about 0.20 to about 0.30 grams of water per gram of dry weight of biological sample.

28. The biological composition of Claim 25 wherein the gradient of the glass transition temperature (degrees C) to the water content (grams of water per gram of dry weight biological sample) ranges from about 75 to about 125 at a water content ranging from about 0.20 to about 0.30 grams of water per gram of dry weight biological sample.

29. The biological composition of Claim 25 wherein a gradient of the glass transition temperature (degrees C) to the water content (grams of water per gram of dry weight of biological sample) ranges from about 700 to about 900 at a water content ranging from about 0.15 to about 0.20 grams of water per gram of dry weight of biological sample.

30. The biological composition of Claim 25 wherein a gradient of the glass transition temperature (degrees C) to the water content (grams of water per gram of dry weight of biological sample) ranges from about 750 to about 850 at a water content ranging from about 0.15 to about 0.20 grams of water per gram of dry weight of biological sample.

31. The biological composition of Claim 25 wherein said preservative comprises an oligosaccharide.

32. The biological composition of Claim 31 wherein said oligosaccharide comprises trehalose.

33. The biological composition of Claim 25 wherein said protein comprises albumin.

34. A process for processing biological samples comprising:
providing a preservative solution having a preservative,
water, and protein;

suspending biological samples in the preservative solution
at a concentration greater than about 10^8 biological samples per
ml. of preservative solution to produce preservative-loaded
biological samples;

freeze-drying the preservative-loaded biological samples;
and

recovering at least 75% of the freeze-dried biological
samples.

35. The process of Claim 34 wherein said preservative solution
comprises from about 60 mM to about 240 mM of said preservative
and from about 2% by weight to about 8% by weight of said
protein.

36. The process of Claim 34 wherein said concentration ranges
from about 0.5×10^9 biological samples per ml preservative
solution to about 10.0×10^9 biological samples per ml
preservative solution.

37. The process of Claim 34 wherein said concentration ranges
from about 0.5×10^9 biological samples per ml preservative
solution to about 10.0×10^9 biological samples per ml

preservative solution, and said recovering includes recovering at least 85% by weight of the freeze-dried biological samples.

38. The process of Claim 34 additionally comprising storing, prior to recovering, the freeze-dried biological samples for more than 600 days.

39. A process for preserving protein structure in a biological sample comprising:

- providing a preservative solution having a preservative, water and protein;

- loading a biological sample with the preservative solution to produce a preservative-loaded biological sample;

- dehydrating the preservative-loaded biological sample while maintaining a residual water content in the biological sample equal to or less than about 0.30 gram of residual water per gram of dry weight biological sample to preserve protein structure of the biological sample upon rehydrating after storage;

- storing the dehydrated preservative-loaded biological sample; and

- rehydrating the stored dehydrated preservative-loaded biological sample with water vapor to preserve protein structure of the biological sample.

40. The process of Claim 39 wherein said rehydrating the stored dehydrated preservative-loaded biological sample with water vapor comprises increasing the water content of the preservative-loaded biological sample until the preservative-loaded biological sample has a water content equal to or less than about 0.30 grams of water per gram of dry weight biological sample.

41. The process of Claim 39 additionally comprising directly hydrating with bulk water the rehydrated preservative-loaded biological sample.

42. A dehydrated composition for mammalian therapy comprising: freeze-dried biological samples comprising a preservative solution for preserving biological properties during freeze-drying and rehydration, wherein said preservative solution includes water, protein, and a preservative, and said biological samples are rehydratable so as to have a normal response to at least one agonist.

43. The dehydrated composition of Claim 42 wherein said normal response to at least one agonists includes a response to thrombin in a physiological concentration commencing at thrombin concentrations ranging from about 0.1 U/ml to about 1.0 U/ml, and wherein between thrombin concentrations ranging from about 0.2 U/ml to about 0.70 U/ml, percent(%) aggregation of the rehydrated biological samples ranges from about 20% to about 80%.

44. The dehydrated composition of Claim 42 wherein said normal response to at least one agonists includes a response to ristocetin in a physiological concentration commencing at ristocetin concentrations ranging from about 1.0 mg/ml to about 10.0 mg/ml.

45. The dehydrated composition of Claim 42 wherein said normal response to at least one agonists includes a response to ristocetin in a physiological concentration and between ristocetin concentrations ranging from about 2.0 mg/ml to about

10.0 mg/ml, percent(%) aggregation of the rehydrated biological samples ranges from about 10% to about 100%.

46. The dehydrated composition of Claim 42 wherein said normal response to at least one agonists includes a response to ristocetin in a physiological concentration and between ristocetin concentrations ranging from about 3.5 mg/ml to about 9.0 mg/ml, percent(%) aggregation of the rehydrated biological samples typically ranges from about 40% to about 90%.

47. The dehydrated composition of Claim 42 wherein said normal response to at least one agonists includes a response to ristocetin in a physiological concentration and between ristocetin concentrations ranging from about 4.0 mg/ml to about 7.0 mg/ml, percent(%) aggregation of the rehydrated biological samples ranges from about 60% to about 80%.

48. A process for loading a preservative into a biological sample comprising:

- providing a preservative solution having a preservative, water and protein;

- disposing a biological sample in the preservative solution for loading the preservative from the preservative solution into the biological sample to produce a preservative-loaded biological sample wherein said preservative solution generally has higher glass transition temperatures than glass transition temperatures for a preservative solution having the preservative, water and no protein; and

- preventing a decrease in a loading efficiency gradient in the loading of the preservative into the biological sample.

49. The process of Claim 48 wherein said preservative comprises an oligosaccharide and said preventing a decrease in a loading efficiency gradient in the loading of the oligosaccharide into the biological sample comprises maintaining a concentration of the oligosaccharide in the oligosaccharide solution below about 50 mM.

50. The process of Claim 48 wherein said loading comprises loading by fluid phase endocytosis.

51. The process of Claim 49 wherein said loading comprises loading by fluid phase endocytosis.

52. The process of Claim 48 wherein said preservative comprises an oligosaccharide and said preventing a decrease in a loading efficiency gradient in the loading of the oligosaccharide into the biological sample comprises maintaining a positive gradient of loading efficiency to concentration of the oligosaccharide in the oligosaccharide solution.

53. The process of Claim 48 wherein said preservative comprises an oligosaccharide and said preventing a decrease in a loading efficiency gradient in the loading of the oligosaccharide into the biological sample comprises maintaining a positive gradient of loading efficiency (%) to concentration (mM) of the oligosaccharide in the oligosaccharide solution.

54. The process of Claim 52 wherein said oligosaccharide comprises trehalose.

55. The process of Claim 53 wherein said oligosaccharide comprises trehalose.

56. A process for loading a preservative into a biological sample comprising:

providing a preservative solution having a preservative, water and protein;

disposing a biological sample in the preservative solution for loading the preservative from the preservative solution into the biological sample to produce a preservative-loaded biological sample wherein said preservative solution generally has higher glass transition temperatures than glass transition temperatures for a preservative solution having the preservative, water and no protein; and

preventing a decrease in a loading gradient in the loading of the oligosaccharide into the biological sample.

57. The process of Claim 56 wherein said preservative comprises an oligosaccharide and said preventing a decrease in a loading gradient in the loading of the oligosaccharide into the biological sample comprises maintaining a concentration of the oligosaccharide in the oligosaccharide solution below about 50 mM.

58. The process of Claim 56 wherein said preservative comprises an oligosaccharide and said loading comprises loading by fluid phase endocytosis.

59. The process of Claim 57 wherein said loading comprises loading by fluid phase endocytosis.

60. The process of Claim 56 wherein said preservative comprises an oligosaccharide and said preventing a decrease in a loading gradient in the loading of the oligosaccharide into the

biological sample comprises maintaining a positive gradient of concentration of oligosaccharide loaded into the biological sample to concentration of the oligosaccharide in the oligosaccharide solution.

61. The process of Claim 60 wherein said oligosaccharide comprises trehalose.